Development and preliminary evidence for the validity of an instrument assessing implementation of human-factors principles in medication-related decision-support systems—I-MeDeSA

Marianne Zachariah,[1] Shobha Phansalkar,[1,2,3] Hanna M Seidling,[4,5] Pamela M Neri,[1] Kathrin M Cresswell,[6] Jon Duke,[7] Meryl Bloomrosen,[8] Lynn A Volk,[1] David W Bates[1,2,3]

[1]Partners HealthCare System, Wellesley, Massachusetts, USA
[2]Division of General Internal Medicine, Brigham and Women's Hospital, Boston, Massachusetts, USA
[3]Harvard Medical School, Boston, Massachusetts, USA
[4]Department of Clinical Pharmacology and Pharmacoepidemiology, University of Heidelberg, Heidelberg, Germany
[5]Division of Medical Information Sciences, University Hospitals of Geneva, Geneva, Switzerland
[6]eHealth Research Group, Centre for Population Health Sciences, University of Edinburgh, Edinburgh, UK
[7]Regenstrief Institute, Indianapolis, Indiana, USA
[8]The American Medical Informatics Association, Bethesda, Maryland, USA

Correspondence to
Dr Shobha Phansalkar, Clinical Informatics Research and Development (CIRD), Partners Healthcare System, 93 Worcester Street, 2nd Floor, Wellesley, MA 02481, USA; sphansalkar@partners.org

Received 9 May 2011
Accepted 22 August 2011
Published Online First 21 September 2011

ABSTRACT

Background Medication-related decision support can reduce the frequency of preventable adverse drug events. However, the design of current medication alerts often results in alert fatigue and high over-ride rates, thus reducing any potential benefits.

Methods The authors previously reviewed human-factors principles for relevance to medication-related decision support alerts. In this study, instrument items were developed for assessing the appropriate implementation of these human-factors principles in drug—drug interaction (DDI) alerts. User feedback regarding nine electronic medical records was considered during the development process. Content validity, construct validity through correlation analysis, and inter-rater reliability were assessed.

Results The final version of the instrument included 26 items associated with nine human-factors principles. Content validation on three systems resulted in the addition of one principle (*Corrective Actions)* to the instrument and the elimination of eight items. Additionally, the wording of eight items was altered. Correlation analysis suggests a direct relationship between system age and performance of DDI alerts ($p=0.0016$). Inter-rater reliability indicated substantial agreement between raters ($\kappa=0.764$).

Conclusion The authors developed and gathered preliminary evidence for the validity of an instrument that measures the appropriate use of human-factors principles in the design and display of DDI alerts. Designers of DDI alerts may use the instrument to improve usability and increase user acceptance of medication alerts, and organizations selecting an electronic medical record may find the instrument helpful in meeting their clinicians' usability needs.

INTRODUCTION

Clinical decision support (CDS) can assist providers in effectively managing patient care. Kuperman *et al* describe medication-related decision support as a type of CDS which offers clinicians guidance for appropriate prescribing in several areas including: drug—allergy checking; dosing guidance; formulary decision support; duplicate therapy checking; drug—drug interaction (DDI) checking; medication-associated laboratory testing; checking of drug—disease interactions and contraindications; and advanced drug—pregnancy alerting.[1] Such guidance can be provided to users through either interruptive alerts or non-interruptive reminders.

When implemented appropriately and accepted by users for prescribing guidance, medication-related decision support can reduce adverse-drug-event (ADE) rates.[2–5] Bates *et al* found that the rate of preventable ADEs decreased from 2.9/1000 patient-days in the absence of medication-related decision support and computerized physician order entry to 1.1/1000 patient-days in the presence of medication-related decision support used in conjunction with computerized physician order entry.[6] In a study by Weingart *et al*, an expert panel was convened to evaluate the extent to which patient harm was avoided through the use of medication-related decision support and DDI alerts. Of the 402 avoided ADEs, 12.2% were serious, 31.1% were significant, and 56.7% were minor.[5] While these results support the positive effects of medication-related decision support on patient safety, it has yet to realize its full potential. This is mainly due to the poor acceptance of warnings among users, as 50% to 95% of drug safety warnings are over-ridden.[7]

Several approaches have been applied to increase alert acceptance. As preliminary steps, van der Sijs *et al* suggest that the number of inappropriate alerts should be reduced and that alerts should be selectively delivered to the appropriate provider. Subsequent steps should address the sensitivity, usefulness, and usability of alerts.[7] Shah *et al* modified a commercial knowledge base to reflect only the most clinically relevant and up-to-date knowledge responsible for triggering DDI alerts, and they decreased the number of interruptive alerts by 71%. Excluding alerts of the highest severity that were implemented as hard-stops, the remaining interruptive alerts resulted in the cancelation (19%) and modification (48%) of orders, indicating a 67% alert acceptance rate.[8] Modifying or canceling the intended order is defined as an acceptance of alert logic, while continuing with an order unchanged after receiving an alert is defined as an over-riding of the alert. In addition to the above-mentioned methods for decreasing alert fatigue, usability and human-factors concepts that facilitate the appropriate use of visual and

text-based information within alerts should be utilized for efficient cognitive processing by the user.[9]

While human factors have been well studied in the general safety literature, few studies have addressed human factors and the design of clinical information systems empirically. In a viewpoint paper, Karsh *et al* stressed the importance of drawing on human-factors engineering to improve the usability of health information technology, calling for such research in the domain of patient safety.[9] Since information presentation affects user behavior and decision-making, information architecture and graphic interface design demand careful consideration. Design details such as navigation from one window to the next, information placement, font size, information similarity, and perceived credibility can significantly affect the user's actions. Saleem *et al* affirm that the user interface stands between clinical information systems and the expected outcome of enhanced patient safety.[10] Improving the design of the human–computer interface through the application of human-factors engineering has the potential to enable users to optimally utilize these systems.

The current literature provides little in the way of tools for assessing the compliance of medication alert design interfaces with commonly employed human-factors principles. In a recent study, Phansalkar *et al* identified 11 key human-factors principles that should be considered when designing medication-related decision support alerts.[11] In the current study, we combined these to build the Instrument for Evaluating Human-Factors Principles in Medication-Related Decision Support Alerts (I-MeDeSA) in order to assess the extent to which a given interface design incorporates these human-factors principles. We then gathered preliminary evidence for the validity of the instrument by testing it on three medication-related decision-support systems. This paper discusses the results of the development and preliminary validation of I-MeDeSA, an instrument created for system developers to improve alert design and to inform an organization's purchase of a usable electronic medical record (EMR) system.

BACKGROUND

Phansalkar *et al* identified key human-factors principles for the design and implementation of medication-related decision support alerts.[11] Eleven principles were determined to be important: Alarm Philosophy, False Alarms, Placement, Visibility, Prioritization, Color, Learnability and Confusability, Textual Information, Habituation, Mental Models, and Proximity of Task Components Being Displayed (table 1).

METHODS

Literature review

A systematic review of the medical informatics literature was conducted to identify any instruments available for quantitatively measuring compliance of clinical information systems with human-factors principles. The PubMed/Medline database was searched for articles published from July 2000 to July 2010. The query consisted of the following criteria: terms related to clinical information systems (*medical records system, medical order entry systems, computerized physician order entry*) along with terms related to human-factors principles (*human-factors engineering, human–interface interactions, usability*), and terms related to instruments (*survey, survey method, questionnaire*). The search was restricted to Meta-Analyses, Practice Guidelines, Randomized-Controlled Trials, or Reviews that were published with abstracts and in English. The search strategy is outlined in figure 1.

The query combining all three search criteria described above returned 159 articles. All abstracts were reviewed by one reviewer (MZ), and 29 articles were selected based on their relevance to the employment of human-factors principles in the design of clinical information systems. One article from a bibliographical search of the selected 29 articles was added. Two reviewers (MZ, SP) independently evaluated the 30 articles to assess whether any of the studies employed an instrument for measuring compliance with human-factors principles in clinical information systems design. Reviewers were unable to identify the existence of such an instrument in the existing literature.

Instrument development

In this study, we developed an instrument to measure the implementation of human-factors principles in the design of medication-related decision support relating to DDI alerts. DDI alerts where chosen to be the focus, since they are one of the most commonly triggered alerts in medication-related decision-support systems. For this purpose, quantifiable human-factors principles as outlined in the previous study by Phansalkar *et al* were compiled, and we created several items for use in assessing these principles. This preliminary version of the instrument was improved and adapted iteratively. First, the instrument was distributed for content validation to three reviewers (KC, PN, and HS) with expertise in the use of human-factors principles for the evaluation of clinical information systems. These experts were asked to review the items for relevance and clarity. Items were eliminated or modified based on feedback received from the three reviewers.

To assess the generalizability of the items to DDI alerts of various designs across different EMR systems, three reviewers (JD, HS, MZ) tested the instrument on DDI alerts generated in EMRs used at their own organizations (ie, (i) Gopher 5.25, an ambulatory EMR used at Regenstrief Institute, Indianapolis, Indiana; (ii) AiDKlinik 1.9.2, a prescribing platform integrated into an ambulatory EMR used at Heidelberg University Hospital, Heidelberg, Germany; and (iii) the Longitudinal Medical Record (LMR) 8.2, an ambulatory EMR used at Partners Healthcare, Boston, Massachusetts). While I-MeDeSA was tested exclusively on outpatient EMRs, the instrument is also applicable to inpatient EMRs, as indicated by a related study that uses the instrument to evaluate the usability of DDI alerts from various inpatient and outpatient EMRs used across the USA.[16] From this study, the authors have observed that the design of inpatient versus outpatient DDI alerts for vendor or home-grown products is similar, and the inclusion of DDI alerts from inpatient decision-support systems would likely result in similar findings.

Reviewers evaluated each unique design of DDI alerts displayed in their organizations' systems. To facilitate the evaluation, reviewers were given exemplar DDIs that were expected to trigger alerts of various levels of severity. They were selected from the drug knowledge database at Partners Healthcare in fall, 2010. The specific DDIs that were provided to the reviewers to examine in their respective systems are presented in table 2.

If these DDIs failed to trigger an alert, reviewers were instructed to use alternate DDIs relevant to their systems in order to capture all severity levels of alerts. Both AiDKlinik and Gopher required alternate and unique DDIs to trigger alerts of various levels available in each system. Feedback from this assessment was used to modify the items so they would be applicable to various DDI alert designs across EMRs.

Next, we assessed inter-rater reliability and construct validity through correlation analysis. Inter-rater reliability was assessed

Table 1 Summary of the 11 key human-factors principles for use in medication-related decision-support alerts, compiled by Phansalkar *et al*[11]

Human-factors principle	Summary of principle
Alarm philosophy	Defined as the logic used to classify alert priority levels. A catalog of all alert level categories should be made available to users, clearly indicating how priority levels are set (eg, based on the severity of patient harm). The goal of this philosophy should be to minimize the overall number of alerts. Additionally, the alert should seek to capture the user's acknowledgment and response. Ideally, the user's acceptance or rejection of the alert would also serve as an acknowledgment of having seen the alert. Less desirable would be alert designs in which these functions are separated, and users would need to first acknowledge an alert and subsequently indicate their response in a separate window.
False alarms	May arise when the alert logic is incorrect or out of date, or the alert is calibrated too sensitively, setting off alarms that are essentially irrelevant to clinical care. False alarms may disrupt workflow and unnecessarily increase workload. Evidence suggests that users will decrease their response to alerts in general as the false-alarm rate increases.[12 13] Recommendations are to move away from alarm strategies that follow a one-size-fits-all approach and toward intelligent alarm monitoring that considers the multi-dimensional relationship between clinical interactions and patient health.
Placement	Alerts and the information within should take into consideration users' viewing habits to optimize visibility. Alerts should be located in the visual field in order of their importance. Additionally, the proximity compatibility principle of Wickens and Carswell[14] should be employed—for example, as a user orders medications, alerts should appear in close proximity to the location on the screen where a user enters medications in the ordering window.
Visibility	Considers overall size of the alert on the screen (target size), luminance, background contrast, and lettering characteristics. The size of the target should be increased as viewing distance increases or contrast decreases. Additionally, letter heights should be larger when reading from a visual display; a mixture of upper and lower cases should be used for easier reading; and visibility is optimized when dark text is presented on a light background.
Prioritization	Prioritization of alerts through visual characteristics is necessary and should utilize hazard matching. This is the process of matching the appearance of the warning to the level of hazard associated with the clinical implications of the alert. For example, colors such as red and orange typically imply a higher level of hazard, while green, blue, and white imply a lower hazard level. It is also important to consider the limitations of color for indicating the level of hazard for color-blind users. To address color-blind users' needs, signal words and shapes can be used to communicate the level of hazard and priority in addition to the use of color. Signal words demonstrating high priority are: 'lethal,' 'deadly,' 'danger;' and words demonstrating low priority are: 'warning,' 'caution,' etc. Shapes can also be used for conveying levels of priority: angular shapes represent high priority while regular shapes such as circles represent low priority.[15]
Color	May be utilized not only to indicate severity but also to communicate the type of alert (eg, drug—drug, drug—allergy, etc) or the response required. However, colors should be kept to a minimum (<10), since, with more colors, it may be difficult for users to remember what each color indicates.
Learnability and confusability	Refers to the ability of the user to learn and distinguish between different types of visual alerts. Color, shapes, and size can be used to lend a distinct appearance to different types of alerts. The fewer features that alerts share with each other, the more distinct they appear, making it easier for users to remember and quickly recognize different types of alerts.
Textual information	Demands as much consideration in the designing of medication-related decision support alerts as the alerts' visual characteristics. The text of visual alerts should possess the following four components for effective communication of information: (1) a signal word to indicate the severity of the alert, (2) a statement of the nature of the hazard (eg, specify interacting drug names or drug classes), (3) an instruction statement providing recommended actions, and (4) a consequence statement that indicates the potential harm to the patient. Of these four components, the nature of the hazard and instruction statements carry the most importance. Additionally, textual information should be explicit, rather than non-explicit (eg, 'smoking causes lung cancer' rather than 'smoking is damaging to health').
Habituation	Refers to a decrease in response to stimulus due to repeated and inconsequential exposure. Habituation predicts that repeated exposure to an alert that does not require that a meaningful response will result in a decrease, and eventual elimination, of responding to the alert. This risk highlights the importance of reducing the rate of false alarms, as well as the importance of an alarm philosophy that minimizes alerts overall. Habituation also highlights the importance of different types of alerts being visually distinct from one another, since alerts that are not visually distinct can be perceived as the same.
Mental model	Represents the understanding individuals have about a particular topic. Given that mental models govern users' behavior, alerting systems should adequately support pervading mental models. For example, since users generally perceive red to mean 'stop' and green to mean 'go,' alerting systems should follow the same model, rather than using green to signal 'stop' and red to signal 'go.'
Proximity of task components being displayed	Incorporates Wickens and Carswell's proximity compatibility principle,[14] as does the *Placement* principle. With respect to *Proximity of Task Components Being Displayed*, tools for decision-making should be integrated into the body of the alert or found within close temporal and spatial proximity to the alert. For example, a link to a medical reference website should be located *within* the alert, not in a window that is multiple clicks away.

using Cohen's κ. Two reviewers (JD, HS) independently evaluated the same DDI alerts from Gopher 5.25. A preliminary evaluation for construct validity was performed by correlating the performance of DDI alerts on I-MeDeSA to the age of the medication decision-support system from which the alerts came. Given that the usability of medication decision support alerts has gained attention only in recent years, we hypothesized that older systems would perform more poorly than newer systems when DDI alerts are evaluated by I-MeDeSA. DDI alerts from LMR (2010) and Gopher (1993) were compared in order to establish a correlation between system age and performance on I-MeDeSA. The scores used for this analysis were the final scores assigned to these systems, as agreed upon by two reviewers (HS, MZ).

The final version of I-MeDeSA incorporated changes made as a result of the above methods for analysis, as well as results from a related study that collected user feedback about various EMRs employed by multiple institutions across the USA.[17] User feedback was used to provide recommendations for the preferred design of DDI alerts and medication-related decision-support systems more generally.

Employing the I-MeDeSA instrument

The instrument has been created for assessment of medication-related decision support alert design. Some medication-related decision-support systems stratify medication alerts based on the severity of patient harm.[18] If the system possesses alerts of various severities, and the designs of these stratified alerts are unique, *each* design would require evaluation, and scores within each item would be averaged. If the design of stratified alerts is the same, or alerts are not stratified, then the user would need to assess only a single design. Each item scores on a binary basis, where a score of 0 is equivalent to answering 'No' for the absence of the characteristic, and a score of 1 is equivalent to answering 'Yes' for its presence. Pilot testing showed that the instrument required approximately 20 min to complete per system.

RESULTS

Eight of the 11 human-factors principles outlined in the Phansalkar *et al* review were selected for incorporation into the instrument because they were quantifiable. Three principles (False Alarms, Habituation, and Mental Models) were excluded

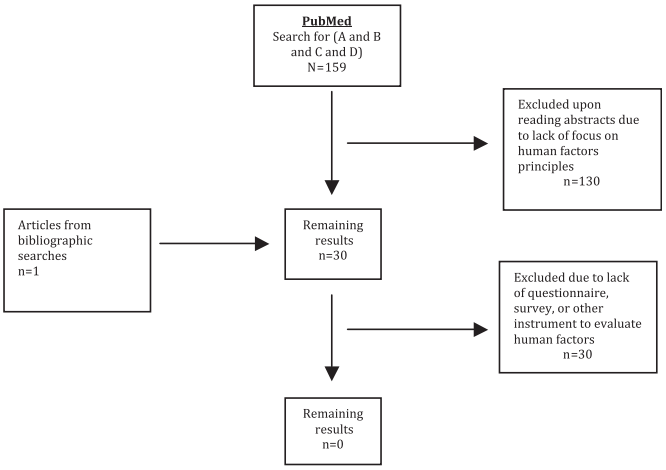

Figure 1 Search criteria and results. (A) (Ambulatory Care Information Systems OR Computerized Order Entry OR Computerized Physician Order Entry OR Computerized Prescriber Order Entry OR Computerized Provider Order Entry OR Decision Support Systems, Clinical OR Drug Therapy, Computer-Assisted OR Electronic Medical Record OR Electronic Order Entry OR Electronic Physician Order Entry OR Electronic Prescribing OR Electronic Prescription OR Medical Order Entry Systems OR Medical Records Systems, Computerized). (B) (Interface, User Computer OR Interface, User–Computer OR Interfaces, User–Computer OR Human Factor OR Human Factors OR Human Factors Engineering OR Human Factors Principles OR Human–Machine Interaction OR Human–Machine Interface Usability OR Interfaces, User Computer OR Usability OR User Computer Interface OR User Computer Interfaces OR User–Computer Interfaces OR User Interface Design). (C) (Instrument* OR Methodology, Survey OR Methods, Survey OR Questionnaire* OR Survey* OR Survey Method OR Survey Methodology). (D) (Limits: Publication Types: Clinical Trial; Meta-Analysis; Practice Guideline; Randomized Controlled Trial; Review; Articles with Abstracts; Language: English; Publication Date Range: July 2000–July 2010).

due to their less quantifiable nature given typical sources of data available, even though these principles may be important for determining user acceptance. Therefore, the initial instrument contained eight principles and 34 allocated items. During the development of I-MeDeSA, the instrument was assessed for content validity and inter-rater reliability, and a preliminary evaluation of construct validity was performed. In testing I-MeDeSA on DDI alerts from three unique EMRs, one new human-factors principle was created (*Corrective Actions*), and eight items across multiple principles were eliminated, resulting in nine principles and 26 items. The formal instrument is available upon request. Detailed information on validation is described below.

Validation

Upon completing the original draft of I-MeDeSA, the instrument was distributed to reviewers (KC, PN, and HS) with expertise in the use of human factors to assess its content validity. After receiving their feedback, changes were made to each principle. Content validation is summarized in table 3. We have also provided a detailed explanation of the *Corrective Actions* principle, since it has not been previously described in the Phansalkar *et al* study.[11]

Corrective actions

Use of this principle serves to streamline the user's workflow in responding to alerts. The goal is to minimize the number of steps the user must take in dealing with an alert, as well as to efficiently capture the user's response to the alert, or intended action. Typically, a user will receive a DDI alert after attempting to place an order for a drug that interacts with an existing drug. As a next step, the user would process the nature of the interaction and weigh the risks and benefits to the patient of continuing with the order or canceling it. At this point, the user usually acknowledges having gone through the assessment process, indicates an acceptance or rejection of the alert, and proceeds with the intended action. The actions may be: to continue with the order unadjusted, to continue with the order but adjust the dose of one of the drugs, to continue with the order but switch to a different drug within the same class, to discontinue an existing drug and place the order for the new drug, or to cancel the order for the new drug and keep the existing drug. Systems considering human-factors principles and usability will provide the user with an efficient means for carrying out any of the steps described for dealing with an alert. The items within the *Corrective Actions* principle capture the use of such efficient methods. The first item assesses the use of a *simplistic* corrective action. Through one click located within the alert, the user is able to simultaneously acknowledge having seen an alert, as well as convey an acceptance or rejection of the alert with respect to their patient. Given the volume of alerts received by clinicians each day and feedback received from users in a related study,[17] the employment of a simplistic method for responding to the alert will increase the usability and efficiency of alerts.

More sophisticated systems will provide *intelligent* corrective actions within the alert. The second item within this principle relates to the interruptive nature of alerts and the fallibility of humans. Intelligent corrective actions address these issues by assisting the user in efficiently accepting or rejecting an alert and carrying out recommended actions. For example, an alert may read, 'Reduce the warfarin dose by 33–50% and follow patient closely.' An alert using intelligent corrective actions would contain a response such as, 'Continue with warfarin order AND reduce dose by 33–50%.' Selecting this option would simultaneously accept the alert and direct the user back to the medication ordering window where the user can adjust the dose appropriately. In addition to automatically linking the user to the ordering screen for adjusting a dose, the system would be

Table 2 Suggested drug interactions provided to reviews

Alert level	Drug–drug interaction	Expected clinical implications
1 (most severe)	Dextoamphetamine and monoamine oxidase inhibitor—for example, isocarboxazid	Patient on amphetamine and a monoamine oxidase inhibitor—increased risk of hypertensive crisis. Concurrent use is contraindicated. Discontinue one of these medications. A washout period of 2 weeks is required for a monoamine oxidase inhibitor.
2 (moderately severe)	Dexfenfluramine and tricyclic antidepressant—for example, amitriptyline	Patient on tricyclic antidepressant and dexfenfluramine. May produce serotonin syndrome. Recommend to avoid concurrent use and to consider an alternative agent.
3 (least severe)	Omeprazole and H_2 blocker—for example, ranitidine	Patient on omeprazole and H_2 blocker. H_2 blocker will render omeprazole inactive. Use with caution.

Table 3 Summary of content validation and the final list of items contained within Instrument for Evaluating Human-Factors Principles in Medication-Related Decision Support Alerts

Human factors principle	Original items	Explanation of changes made during content validation	Final items
Alarm philosophy	(1i) Is there a description of the logic underpinning the classification of an event as unsafe (eg, a catalog of unsafe events, correlating the level of the alert with the severity of the consequences)?	Reviewers felt Items 1i and 1ii were redundant. Therefore, these two items were combined to capture whether or not alert logic was available to the user.	(1i) Does the system provide a general catalog of unsafe events, correlating the priority level of the alert with the severity of the consequences?
	(1ii) Is the documentation obvious or available to the user?		
	(1iii) Are corrective actions available to allow the user to acknowledge or cancel the alert?	Items 1iii—1v pertained to design features that assist in streamlining workflow in responding to alerts. Reviewers felt items relating to alert response deserved their own principle; thus *Corrective Actions* was created to reflect these items (see *Corrective Actions* below).	
	(1iv) Is the users' response to the alert the appropriate corrective action and not merely an acknowledgment of having seen the alert?		
	(1v) Are the corrective actions easy to perform?		
Placement	(2i) Are different types of alerts meaningfully grouped (eg, by medication order where all of the alerts related to a specific medication order should be grouped together or by type where all of the allergy alerts are grouped together)?	Further clarification given through provided example	(2i) Are different types of alerts meaningfully grouped (eg, by the severity of the alert, where all Level 1 alerts are placed together, or by medication order, where alerts related to a specific medication order are grouped together)?
	(2ii) Is the response to the alert located in close proximity to the event that is, triggering the alert?	Further clarification given through provided example	(2ii) If available, is the response to the alert, indicating the user's intended action (eg, Accept, Cancel/Over-ride), provided along with the alert, as opposed to being located in a different window or in a different area on the screen?
	(2iii) Is the alert linked with the medication order by an appropriate timing? (eg, does the alert appear immediately after the medication is selected?).	Further clarification given through provided example	(2iii) Is the alert linked with the medication order by an appropriate timing (eg, DDI alert appears as soon as a contraindicated drug is chosen and does not wait for the user to complete the order and then alert him/her on a possible interaction)?
	(2iv) Are the alerts centered on the screen or placed in a location that allows the user to see them easily?	This item was modified to provide an objective guideline for judging the layout of information contained within the alert. Reviewers felt the subjectivity of the original item failed to provide an objective assessment and was too open to interpretation.	(2iv) Does the layout of critical information contained within the alert facilitate quick uptake by the user? Critical information should be placed on the first line of the alert or closest to the left side of the alert box. Critical information should be labeled appropriately and must consist of: (1) the interacting drugs, (2) the risk to the patient, and (3) the recommended action. (Note: information contained within resources such as an 'Infobutton' or link to a drug monograph does not equate to information contained within the alert.)
	(2v) Are the alerts placed on the screen in the order of their importance? The highest-priority alerts should be located where users tend to focus most.	This item was transferred to the *Prioritization* principle, since it relates to placing the highest priority alerts in a manner that allows them to be seen without the user having to scroll through the window	
	(2vi) Are recommended actions immediately accessible (eg, ordering a potassium lab when alerted for hyperkalemia)?	This item more closely relates to *Corrective Actions* and has been removed from *Placement* and incorporated as the second item in the new principle	

Continued

Table 3 Continued

Human factors principle	Original items	Explanation of changes made during content validation	Final items
Visibility	(3i) Is the size of the alert message able to draw the attention of the user?	Since responses to this item could vary based on personal preference, the item was altered to more objectively measure the alert's ability to draw attention through the use of a variety of methods such as borders, highlighting, etc, in addition to size	(3i) Is the area where the alert is located distinguishable from the rest of the screen? This might be achieved through the use of a different background color, a border color, highlighting, bold characters, occupying the majority of the screen, etc.
	(3ii) Does the background contrast allow the user to easily read the alert message (eg, dark text on a light background is easier to read than light text on a dark background)?	No significant changes made to the item	(3ii) Is the background contrast sufficient to allow the user to easily read the alert message (eg, dark text on a light background is easier to read than light text on a dark background)?
	(3iii) Is the font used to display the textual message appropriate for the user to read the alert easily (eg, a mixture of upper and lower case lettering is easier to read than upper case only)?	No significant changes made to the item	(3iii) Is the font used to display the textual message appropriate for the user to read the alert easily (eg, a mixture of upper- and lower-case lettering is easier to read than upper case only)?
	(3iv) Is there consideration given to placing the alert so as to reduce the screen glare and reflection, which can diminish legibility?	Reviewers determined this item was unrelated to the usability *of alerts*, so this item has been removed	
Prioritization	(4i) Is the prioritization of alerts indicated appropriately by color (eg, colors such as red and orange imply a high priority when compared to colors such as green, blue and white)?	No significant changes made to the item	(4i) Is the prioritization of alerts indicated appropriately by color (eg, colors such as red and orange imply a high priority when compared to colors such as green, blue, and white)?
	(4ii) Does the alert use prioritization with green and red colors which may not take into consideration users who may be colorblind?	This item was reworded so that answering in the affirmative indicates the use of this human-factors principle	(4ii) Does the alert use prioritization with colors other than green and red, to take into consideration users who may be colorblind?
	(4iii) Are signal words used appropriately in the alert (eg, 'warning' and 'caution' should be used to denote medium levels of hazard, while terms like 'note' or 'notice' are used to denote lower levels of hazard)?	Further clarification given through the wording of this item and the provided example	(4iii) Are signal words appropriately assigned to each existing level of alert (eg, 'Warning' would appropriately be assigned to a Level 1 alert and not a Level 3 alert)? 'Note' would appropriately be assigned to a Level 3 alert, and not a Level 1 alert.
	(4iv) Does the alert utilize shapes or icons in order to indicate the priority of the alert (eg, angular and unstable shapes such as an inverted triangles indicate higher levels of priority than regular shapes such as circles)?	No significant changes made to the item	(4iv) Does the alert utilize shapes or icons in order to indicate the priority of the alert (eg, angular and unstable shapes such as inverted triangles indicate higher levels of priority than regular shapes such as circles)?
		Originally Item 2v, this item has been moved to the *Prioritization* principle. Further clarification given through provided example.	(4v) In the case of multiple alerts, are the alerts placed on the screen in the order of their importance? The highest-priority alerts should be visible to the user without having to scroll through the window.
Color	(5i) Does the alert utilize color coding to indicate the type of unsafe event (eg, DDI vs allergy alert)?	No significant changes made to the item	(5i) Does the alert utilize color coding to indicate the type of unsafe event (eg, DDI vs allergy alert)?
	(5ii) Does the alert utilize color coding to indicate the severity of risk (eg, Level 1 vs level 2)?	This item was removed, since the notion of conveying prioritization of the severity of alerts through the use of color has already been captured as Item 4i in the *Prioritization* principle	
	(5iii) Does the alert utilize color coding to indicate the response required (eg, a hard stop vs an alert that you can over-ride)?	Reviewers determined that color-coding the type of response required could be better addressed through mechanisms other than color. This item was removed.	
	(5iv) Is there excessive coloring used on the screen (eg, colors should be kept to fewer than 10)?	This item was reworded so that answering in the affirmative indicates the use of this human factors principle	(5ii) Is color minimally used to focus the attention of the user? Excessive coloring used on the screen can create noise and distract the user. Therefore, colors should be kept to fewer than 10.
	(5v) Is the color used for the textual message in the alert appropriate and easy to read?	Reviewers removed this item, since it has been captured in the *Visibility* and *Prioritization* principles, Items 3iii and 4i	

Continued

Table 3 Continued

Human factors principle	Original items	Explanation of changes made during content validation	Final items
Learnability and confusability	(6i) Do the different *types* of alerts look easily distinguishable from one another?	This item has been eliminated, since it has already been captured in the *Color* principle as Item 5i in a more specific manner.	
	(6ii) Do the different *levels* of alerts look easily distinguishable from one another?	Further clarification given through provided example	(6i) Are the different severities of alerts easily distinguishable from one another? For example, do major alerts possess visual characteristics that are distinctly different from minor alerts? The use of a signal word to identify the severity of an alert is not considered to be a visual characteristic.
Text-based information	(7i) Does the alert possess the following four information components?		(7) Does the alert possess the following four information components?
	(7ia) A signal word to indicate the priority of the alerts (eg, 'note,' 'warning,' or 'danger')?	No significant changes made to the item	(7i) A signal word to indicate the priority of the alert (eg, 'note,' 'warning,' or 'danger')?
	(7ib) A statement of the nature of the hazard describing why the alert is shown?	Further clarification given through provided example	(7ii) A statement of the nature of the hazard describing why the alert is shown? This may be a generic statement in which the interacting classes are listed, or an explicit explanation in which the specific drug—drug interactions are clearly indicated.
		The original Item 7iii became subitem 7iia	(7iia) If yes, are the specific interacting drugs explicitly indicated?
	(7ic) An instruction statement telling the user how to avoid the danger or the desired action?	No significant changes made to the item	(7iii) An instruction statement telling the user how to avoid the danger or the desired action?
		The original Item 7iv became subitem 7iiia	(7iiia) If yes, does the order of recommended tasks reflect the order of required actions?
	(7id) A consequence statement telling the user what might happen if the instruction information is ignored?	Further clarification given through provided example	(7iv) A consequence statement telling the user what might happen—for example, the reaction that may occur, if the instruction information is ignored
	(7ii) Does the consequence statement contain definitive, rather than probabilistic, statements?	Reviewers determined that it is not possible to provide a definitive consequence statement, since such certainty cannot be applied to every unique patient. Therefore, this item has been eliminated.	
	(7iii) Does the message provide explicit information on why the alert was generated (eg, identifying specific drug which caused the alert rather than only providing the drug class)?	This item has been removed, but the content has been captured in Item 7iia	
	(7iv) Does the order of words in the recommendation reflect the order of required actions?	This item has been removed, but the content has been captured in Item 7iiia	
Proximity of task components being displayed	(8i) Are the information components required for decision-making displayed within the alert or present close together spatially or temporally?	Further clarification given through provided example	(8i) Are the informational components needed for decision-making on the alert present either within or in close spatial and temporal proximity to the alert? For example, is the user able to access relevant information directly from the alert, that is a drug monograph, an 'Infobutton,' or a link to a medical reference website providing additional information?

Continued

Table 3 Continued

Human factors principle	Original items	Explanation of changes made during content validation	Final items
Corrective actions		The original Items 1iii and 1iv from *Alarm Philosophy* were combined to form the first item in the *Corrective Actions* principle	(9i) Does the system possess corrective actions that serve as an acknowledgment of having seen the alert while simultaneously capturing the user's intended action? For example, 'Accept' and 'Cancel'/'Over-ride' are corrective actions that convey the user's acceptance or rejection of alert logic, while 'OK' is only an acknowledgment of the user having seen the alert.
		The original Item 1v from *Alarm Philosophy* became Item 9ia. It has also been worded more clearly, and an example has been provided.	(9ia) If yes, does the alert utilize intelligent corrective actions that allow the user to complete a task? For example, if warfarin and ketoconazole are co-prescribed, the alert may ask the user to 'Reduce the warfarin dose by 33—50% and follow the patient closely.' An intelligent corrective action would be 'Continue with warfarin order AND reduce dose by 33—50%.' Selecting this option would simultaneously accept the alert AND direct the user back to the medication ordering window where the user can adjust the dose appropriately.
		Based on information gathered from a related study,[17] reviewers created this last item	(9ii) Is the system able to monitor and alert the user to follow through with corrective actions? Referring to the previous example, if the user tells the system that he/she will reduce the warfarin dose but fails to follow through on that promise, does the system alert the user?

DDI, drug—drug interaction.

capable of automatically discontinuing an existing drug directly from the alert, as well as replacing an order for a different drug within the same class (and medication decision support would re-evaluate interactions with the newly selected drug). Given that clinicians are already juggling the care of multiple patients, and given the nature of alerts to interrupt the user's workflow, such intelligent corrective actions are important. The user would not have to remember to go back into the system, after dealing with all alerts, to follow through with intended actions. Finally, there would ideally exist a fail-safe mechanism in which the system is capable of monitoring whether or not the user followed through with the intended action, the third item in this principle. If the user did not complete intended actions, the system would notify the user.

Instrument applicability

To ensure the applicability of the instrument to a variety of DDI alert designs, the modified instrument was distributed to three reviewers (JD, HS, and MZ). One reviewer had expertise in the field of medical informatics; another in the use of human-factors principles; and the third with experience in the usability of CDS systems. Reviewers tested the instrument on the DDI alerts available in the EMRs used at their own institutions. The design of DDI alerts was different for each system. See table 4 for a brief description of DDI alerts from each system.

After reviewing the evaluations and associated feedback from reviewers, the following guidelines for scoring the instrument items were established to maximize applicability to different systems:

Critical Information Layout (Item 2iv): The primary focus of this item is on the *layout* of the information presented within the alert. Critical information provided in a DDI alert must include: (1) the interacting drugs, (2) the risk to the patient, and (3) the recommended action. Each component should be labeled appropriately and located on a few lines each, at the first point of alerting. The information should not be presented together in one paragraph. If any of the critical information components require the user to click through additional screens or to sort through a drug monograph to access this information, this critical information layout item will be scored as zero. Systems will score higher if they use active alerts that force users to see alert information, rather than passive alerts where the user must seek out alert information through multiple clicks, effectively allowing the user to avoid the information entirely.

Visibility (Item 3iii): Any mixture of upper and lower case shall be scored as 1; exclusive use of either upper *or* lower case shall be scored as 0.

Distinguishing Alert Features (Item 6i): To achieve a score of 1, alerts must possess *unique visual characteristics*, such as color, shapes, and font. The use of a signal word to identify the severity of the alert is not considered to be a visual characteristic.

Text-Based Information (Items 7i—7iv): These items evaluate the textual information presented at the first point of alerting. Any information contained within expanded details or a monograph shall be disregarded. If the user is initially presented with only one component of an alert, for example, only the type or severity, and they must click through additional windows or read through a monograph to acquire the required information, the corresponding items shall be scored as 0.

Corrective Actions (Item 9ia): If there is at least one corrective action presented in the alert, such as 'discontinue existing drug,' this item shall receive a score of 1.

The patient safety literature has indicated the importance of providing users with information on how alert severities are

Table 4 Description of drug—drug interaction alerts from three electronic medical records

Principle	AiDKlinik	Gopher	Longitudinal Medical Record
Alarm philosophy	Although no catalog is visible for the user that explains in detail the levels of severity, alerts are color-coded and contain a brief description to convey priority	Alerts are not stratified by levels of severity	Although no catalog exists explaining the levels of alert severity, alerts are color-coded to convey priority
Placement	Alerts are placed in order of severity (from most severe to least severe top to bottom); alerts appear upon selecting the drug; the alert presents a description of the potential adverse event (including the mechanism of the interaction) and its clinical management; the user must scroll through the screen to see all alerts	Since alerts are not stratified by levels of severity, alerts are not grouped according to severity. As you place an order for drug A, alerts appear for interactions between current meds and drug A. You will not, for example, see an interaction for X—Z while you are placing an order for drug A. The response to the alert is located within the alert. The alert clearly indicates the interacting drugs and provides a link to additional information on the interaction.	Alerts are stratified by three levels of severity; responses are contained within the alerts with the highest levels of severity (the least severe alert is informational only); alerts appear as drugs are ordered; interacting drugs are specified, and clinical management and consequence statements are conveyed within a total of 4.5 lines
Visibility	Each alert is outlined in the color that signifies the appropriate severity; the text is blue on a white background; the font is easily legible	The alerts appear on top of the ordering screen; the area naming the interaction displays yellow text is written on a blue background, and the area displaying the response is black text written on a gray background; font is easily legible	Levels 1 and 2 alerts appear occupying the entire screen, interrupting the user's workflow; level 3 alert is informational and is found within the ordering screen; for level 1 alert: blue text on pale red background; for level 2 alert: black text on pale yellow background; for level 3 alert: red text on white background; font is easily legible
Prioritization	Alerts are color-coded by severity (black, red, orange, yellow, green, and purple); signal words are used to convey the severity of the alert; an exclamation point is used for the highest level of severity, along with color and a signal word; highest severity alerts are located at the top of the listed alerts	Neither color, signal words, nor shapes or icons are used to signify the alert's priority; all alerts possess the same visual characteristics and appear as drugs orders are placed	Level 1 alert is red; level 2 alert is orange; level 3 alert is red text incorporated into the ordering screen; level 1 alerts labeled 'Critical,' level 2 alerts labeled 'Warning,' level 3 alert labeled 'Alert;' no shapes or icons are used to convey alert priority; level 1 alerts appear first, followed by level 2 alerts; level 3 alerts appear on the ordering screen in a non-interruptive manner
Color	Alerts are color-coded by severity, not by the type of alert; no more than seven colors are used for each alert	Color coding within the alert is not utilized in any way; the alert utilizes no more than four colors	Alerts are color-coded by severity, not by type; alerts utilize no more than 10 colors
Learnability and confusability	The highest severity alert possesses three visual cues to convey its importance (color, signal word, and a small icon), while lower severity alerts use two visual cues (color and signal word)	All alerts, regardless of severity, possess the same visual characteristics	Alerts are color-coded by severity level: level 1 is red, and level 2 is orange
Text-based information	The alert displays a signal word indicating its severity level; the interacting drugs are specifically indicated; the effects of the interaction and clinical management are clearly and succinctly displayed	All alerts are labeled with 'Warning;' the interacting drugs are specified; the user is able to continue with the order, see more information about interactions, or back out of the order; the additional information succinctly presents the user with the effect, mechanism, clinical significance, and management of the interaction	Level 1 and 2 alerts are accompanied by a signal word indicating priority level; interacting drugs are specified, along with the effect of the interaction and suggested clinical management, all within 4.5 lines
Proximity of task components being displayed	The user can access the drug monograph through a button contained within each alert	The user can link to outside sources of information from elsewhere in the system when connected to a workstation, but there is no link within the alert	On the ordering screen, current interactions are listed, along with a link to Micromedex for obtaining additional information from an outside source
Corrective actions	All alerts only present information, and no alerts require action; the system is not capable of ensuring that the user follows through with the recommended clinical management	Directly from the alert, the user can choose to continue with or cancel the order of the offending drug; no other actionable options are available, and the system is not capable of ensuring that the user follows through with the recommended clinical management	Actionable options within an alert depend on the severity level; for level 1, the user is forced to eliminate one of the offending drugs; for level 2, the user may choose to discontinue the pre-existing drug or continue with an order by providing an over-ride reason; only for level 1 alerts is the system able to ensure that the user follows through with the recommended clinical management

assessed and the general 'alert philosophy' of the system. The absence of such information existed across systems, creating a lack of transparency for users to assess severity ratings, the number of levels of alerts, and general information. Users have expressed the desire for such a catalog in order to increase DDI alert usability.[17] Therefore, authors felt the presence of item 1i was an important criterion to include.

Inter-rater reliability

Two reviewers (JD, HS) independently applied I-MeDeSA to DDI alerts of Gopher 5.25. Their ratings were compared, and Cohen's κ was calculated (κ=0.764, 95% CI 0.519 to 0.999). The calculated κ value indicates substantial agreement between raters.

Correlation analysis

Preliminary evidence for construct validity was gathered through a correlation analysis. Given that the usability of medication-related decision support alerts has gained attention only in recent years, we hypothesized that older systems would perform more poorly than newer systems when DDI alerts are evaluated by I-MeDeSA. DDI alerts from LMR (2010) and Gopher (1993) were compared in order to establish a correlation between system age and performance on I-MeDeSA. Analysis

suggests a direct correlation between system age and performance of DDI alerts on I-MeDeSA. LMR (2010) performed better than Gopher (1993) (p=0.0016). However, this is only preliminary evidence for known group difference. A larger sample size is necessary to determine a true correlation between system age and performance of DDI alerts on I-MeDeSA.

DISCUSSION

Although there has been discussion surrounding the importance of human factors in medication-related decision support, relatively little empirical research has been done. The human-factors studies in this domain have largely been qualitative, and instruments to assess how human-factors principles have been incorporated have not been widely available. Therefore, we developed an instrument that evaluates the usability of DDI alerts within medication-related decision-support systems, combining previous research on human-factors principles with current user feedback, thus making I-MeDeSA a novel tool.

Eight of the nine human-factors principles (*Alarm Philosophy, Placement, Visibility, Prioritization, Color, Learnability and Confusability, Text-Based Information,* and *Proximity of Task Components Being Displayed*) selected for use in I-MeDeSA were originally reported on in a study by Phansalkar *et al*,[11] which compiled information on human-factors principles and alert design and display from a wide variety of robust sources. A ninth principle was created from a combination of other items and user feedback collected in a related study.[17] Twenty-six items were created from the nine selected human-factors principles, and preliminary evidence for the validity of the instrument was gathered.

While the assessment of content validity and inter-rater reliability were relatively straightforward, construct validation proved to be quite challenging, given the limited number of decision-support systems we could assess. Ideally, a larger sample size of EMRs would allow performance of analyses to assess the construct validity (eg, factor analysis) and internal consistency reliability. However, factor analysis requires that we test I-MeDeSA on two to 10 times as many systems as there are items, that is, 52–260 decision-support systems. Additionally, Cronbach's α should have at least 20 observations per item in order to produce a reliable assessment of internal consistency. As part of a larger study, we have assessed the use of human-factors principles in 14 medication decision-support systems (both inpatient and outpatient) used throughout the USA.[16] We felt it would be inappropriate to test I-MeDeSA on all 14 systems. Rather, we selected approximately 20% of the 14 systems as representative examples to test the instrument.

To offer additional support for the validity of I-MeDeSA, Seidling *et al* confirmed that the display of an alert and the textual information within are related to the user's acceptance of an alert.[19] Again, alert acceptance is defined as the modification or cancelation of an order upon receiving an alert. The alert display had an OR of 4.23 (95% CI 1.78 to 10.08, p=0.0011) for canceled orders versus over-ridden alerts, and an OR of 4.78 (95% CI 4.63 to 4.93, p<0.0001) for modified orders versus over-ridden alerts. The content of all nine items associated with alert display can be found within I-MeDeSA. Textual information had an OR of 1.22 (95% CI 1.15 to 1.30, p<0.0001) for modified orders versus over-ridden alerts.

Our hope is that designers with little or no knowledge of human-factors principles may use this instrument during early stages of development to help construct highly usable DDI alerts. We believe the instrument will be especially useful to designers with little access to users who can test the product for usability. Additionally, I-MeDeSA may assist institutions and individual clinical practices in selecting a suitable medication-related decision support vendor product.

I-MeDeSA has been tested on DDI alerts only and has not been tested on other types of medication alerts, such as drug-allergy alerts and drug-duplicate alerts. To continue increasing the usability of medication-related decision-support systems and enhancing patient safety, similar work should be carried out in other areas.

LIMITATIONS

I-MeDeSA assesses the usability of DDI alerts used by outpatient EMRs with medication-related decision-support functionality. While only three systems were used to test the generalizability of I-MeDeSA, these three systems presented a variety of DDI alert designs.

The scope of the study limited our evaluation to outpatient EMRs, but we do think these findings are relevant to EMRs used in inpatient care, as well as to other types of medication-related decision support beyond DDIs. Future research will focus on validating this instrument on EMRs used in different settings, including inpatient and personal health records and other types of medication decision-support alerts. Expansion of the number of EMRs evaluated will also allow us to perform more stringent analyses to support factor analysis or to obtain a reliable assessment of internal consistency of the instrument.

CONCLUSIONS

We developed I-MeDeSA to assess the use of human-factors principles in the design of DDI alerts. In the future, further validation should be performed and I-MeDeSA's use should be evaluated for other types of decision support. We hope that implementation of I-MeDeSA will assist in the system-development process and increase the usability and effectiveness of DDI alerts.

Acknowledgments The authors would like to thank D Seger and J Warvel, for their assistance in supporting the evaluation of selected EMRs, and S Lipsitz and EF Cook, for their invaluable advice and support on this study.

Funding This study was sponsored by the Center for Education and Research on Therapeutics on Health Information Technology grant (Principal Investigator: DWB), Grant # U18HS016970 from the Agency for Healthcare Research and Quality.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1. **Kuperman GJ,** Bobb A, Payne TH, *et al*. Medication-related clinical decision support in computerized provider order entry systems: a review. *J Am Med Inform Assoc* 2007;**14**:29–40.
2. **Kuperman GJ,** Teich JM, Gandhi TK, *et al*. Patient safety and computerized medication ordering at Brigham and Women's Hospital. *Jt Comm J Qual Improv* 2001;**27**:509–21.
3. **McCoy AB,** Waitman LR, Gadd CS, *et al*. A computerized provider order entry intervention for medication safety during acute kidney injury: a quality improvement report. *Am J Kidney Dis* 2010;**56**:832–41.
4. **Rommers MK,** Zegers MH, De Clercq PA, *et al*. Development of a computerised alert system, ADEAS, to identify patients at risk for an adverse drug event. *Qual Saf Health Care* 2010;**19**:1–6.
5. **Weingart SN,** Simchowitz B, Padolsky H, *et al*. An empirical model to estimate the potential impact of medication safety alerts on patient safety, health care utilization, and cost in ambulatory care. *Arch Intern Med* 2009;**169**:1465–73.
6. **Bates DW,** Teich JM, Lee J, *et al*. The impact of computerized physician order entry on medication error prevention. *J Am Med Inform Assoc* 1999;**6**:313–21.
7. **van der Sijs H,** Aarts J, Vulto A, *et al*. Overriding of drug safety alerts in computerized physician order entry. *J Am Med Inform Assoc* 2006;**13**:138–47.

8. **Shah NR,** Seger AC, Seger DL, *et al*. Improving acceptance of computerized prescribing alerts in ambulatory care. *J Am Med Inform Assoc* 2006;**13**:5—11.
9. **Karsh BT,** Weinger MB, Abbott PA, *et al*. Health information technology: fallacies and sober realities. *J Am Med Inform Assoc* 2010;**17**:617—23.
10. **Saleem JJ,** Russ AL, Sanderson P, *et al*. Current challenges and opportunities for better integration of human factors research with development of clinical information systems. *Yearb Med Inform* 2009:48—58.
11. **Phansalkar S,** Edworthy J, Hellier E, *et al*. A review of human factors principles for the design and implementation of medication safety alerts in clinical information systems. *J Am Med Inform Assoc* 2010;**17**:493—501.
12. **Bliss JP,** Gilson RD, Deaton JE. Human probability matching behaviour in response to alarms of varying reliability. *Ergonomics* 1995;**38**:2300—12.
13. **Bliss JP,** Dunn MC. Behavioural implications of alarm mistrust as a function of task workload. *Ergonomics* 2000;**43**:1283—300.
14. **Wickens C,** Carswell C. The proximity compatibility principle: its psychological foundation and relevance to display design. *Hum Factors Aero Saf* 1995;**37**:473—94.
15. **Riley M,** Cochran D, Ballard J. Investigation into the preferred shapes for warning labels. *Hum Factors Aero Saf* 1982;**24**:737—42.
16. **Zachariah M,** Phansalkar S, Seidling HM, *et al*. Evaluation of medication alerts for compliance with human factors principles: a multi-center study. *AMIA Annu Symp Proc* 2011.
17. **Phansalkar S,** Zachariah M, Cresswell K, *et al*. A qualitative approach to assessing medication-related alerting in electronic medical records. *Society of General Internal Medicine Annual Meeting*, 2011.
18. **Paterno MD,** Maviglia SM, Gorman PN, *et al*. Tiering drug—drug interaction alerts by severity increases compliance rates. *J Am Med Inform Assoc* 2009;**16**:40—6.
19. **Seidling HM,** Phansalkar S, Seger DL, *et al*. Factors influencing alert acceptance: a novel approach for predicting the success of clinical decision support. *J Am Med Inform Assoc* 2011;**18**:479—84.